

Experiment Number: 20406-01
Test Type: 1-YEAR
Route: SKIN APPLICATION
Species/Strain: Mouse/SKH-1/NCTR

**P18: INCIDENCE RATES OF NON-NEOPLASTIC LESIONS BY ANATOMIC SITE (a) WITH
AVERAGE SEVERITY GRADES[b]**
Test Compound: Aloe phototoxicity studies
CAS Number: ALOEPHOTOTOX

Date Report Requested: 10/23/2014
Time Report Requested: 13:10:40
First Dose M/F: NA / NA
Lab: NCTR

C Number:	C20406
Lock Date:	Not Entered.
Cage Range:	All
Date Range:	All
Reasons For Removal:	All
Removal Date Range:	All
Treatment Groups:	All
Study Gender:	Male
PWG Approval Date	NONE

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SKH-1/NCTR Mouse MALE	NOCREAM NO_SSL	VEHICLE NO_SSL	ALOGEL6% NO_SSL	WHLEAF6% NO_SSL	CHARCL6% NO_SSL	AEMOD_HI NO_SSL
Disposition Summary						
Animals Initially In Study	36	35	36	36	36	35
Early Deaths						
Accidentally Killed			1			
Moribund Sacrifice		5	1	4	3	7
Natural Death	1			1	2	
Survivors						
Moribund Sacrifice						
Natural Death				1		
Terminal Sacrifice	35	30	34	30	30	27
Harvest					1	1
Animals Examined Microscopically	36	35	36	35	36	35

ALIMENTARY SYSTEM

None

CARDIOVASCULAR SYSTEM

None

ENDOCRINE SYSTEM

None

GENERAL BODY SYSTEM

None

GENITAL SYSTEM

None

HEMATOPOIETIC SYSTEM

None

INTEGUMENTARY SYSTEM

a - Number of animals examined microscopically at site and number of animals with lesion

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

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SKH-1/NCTR Mouse MALE	NOCREAM NO_SSL	VEHICLE NO_SSL	ALOGEL6% NO_SSL	WHLEAF6% NO_SSL	CHARCL6% NO_SSL	AEMOD_HI NO_SSL
Skin, Control	(36)	(35)	(36)	(35)	(36)	(35)
Abscess						
Cyst Epithelial Inclusion	2	3	1	3	4	3
Dermis, Inflammation, Chronic Active	34 [1.7]	31 [1.7]	34 [1.9]	32 [1.7]	36 [1.8]	32 [1.8]
Developmental Malformation						
Epidermis, Necrosis	2 [3.5]		1 [4.0]	1 [4.0]	1 [4.0]	
Granuloma						
Hyperplasia, Squam Atypical, Focal, One						
Hyperplasia, Squamous	2 [3.0]	2 [1.5]	2 [1.5]	1 [2.0]	1 [2.0]	
Inflammation, Pyogranulomat	3 [3.0]		3 [3.0]	3 [2.7]	3 [4.0]	
Subcut Tiss, Edema						
Skin, Site Of Application	(0)	(2)	(0)	(1)	(0)	(2)
Skin, Site of Application	(36)	(33)	(36)	(34)	(36)	(33)
Abscess						
Cyst Epithelial Inclusion	1	2	4	3	5	9
Dermis, Inflammation, Chronic Active	36 [1.6]	33 [1.6]	36 [1.8]	34 [1.7]	36 [1.8]	33 [1.9]
Epidermis, Necrosis		1 [4.0]			1 [4.0]	
Granuloma				1		
Hyperplasia, Squam Atypical, Focal, > Five						
Hyperplasia, Squam Atypical, Focal, Five						
Hyperplasia, Squam Atypical, Focal, Four						
Hyperplasia, Squam Atypical, Focal, One						1
Hyperplasia, Squam Atypical, Focal, Three						
Hyperplasia, Squam Atypical, Focal, Two						
Hyperplasia, Squamous	1 [1.0]	1 [2.0]	1 [1.0]		1 [2.0]	1 [1.0]
Inflammation, Pyogranulomat					1 [4.0]	
Subcut Tiss, Inflammation, Pyogranulomat						

MUSCULOSKELETAL SYSTEM

a - Number of animals examined microscopically at site and number of animals with lesion
 b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

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SKH-1/NCTR Mouse MALE	NOCREAM NO_SSL	VEHICLE NO_SSL	ALOGEL6% NO_SSL	WHLEAF6% NO_SSL	CHARCL6% NO_SSL	AEMOD_HI NO_SSL
None						
NERVOUS SYSTEM						
None						
RESPIRATORY SYSTEM						
None						
SPECIAL SENSES SYSTEM						
None						
URINARY SYSTEM						
None						

a - Number of animals examined microscopically at site and number of animals with lesion
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SKH-1/NCTR Mouse MALE	NOCREAM 6.85SSL	NOCREAM 13.7SSL	VEHICLE 13.7SSL	ALOGEL3% 13.7SSL	ALOGEL6% 13.7SSL	WHLEAF3% 13.7SSL
Disposition Summary						
Animals Initially In Study	36	36	35	36	36	36
Early Deaths						
Accidentally Killed	1					
Moribund Sacrifice	5		3	5	1	1
Natural Death	2		1			2
Survivors						
Moribund Sacrifice	1					
Natural Death						
Terminal Sacrifice	22					1
Harvest	5	36	31	31	35	32
Animals Examined Microscopically	36	36	35	36	36	36
ALIMENTARY SYSTEM						
None						
CARDIOVASCULAR SYSTEM						
None						
ENDOCRINE SYSTEM						
None						
GENERAL BODY SYSTEM						
None						
GENITAL SYSTEM						
None						
HEMATOPOIETIC SYSTEM						
None						
INTEGUMENTARY SYSTEM						
Skin, Control	(36)	(36)	(35)	(36)	(36)	(36)

a - Number of animals examined microscopically at site and number of animals with lesion
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Date Report Requested: 10/23/2014

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First Dose M/F: NA / NA

Lab: NCTR

SKH-1/NCTR Mouse MALE	NOCREAM 6.85SSL	NOCREAM 13.7SSL	VEHICLE 13.7SSL	ALOGEL3% 13.7SSL	ALOGEL6% 13.7SSL	WHLEAF3% 13.7SSL
Abscess	2 [4.0]	1 [4.0]		1 [4.0]		1 [4.0]
Cyst Epithelial Inclusion	4	4	4	3	3	
Dermis, Inflammation, Chronic Active	30 [1.5]	22 [1.1]	30 [1.1]	26 [1.4]	30 [1.3]	31 [1.4]
Developmental Malformation				1		
Epidermis, Necrosis		1 [4.0]	1 [4.0]	3 [3.3]	1 [3.0]	
Granuloma					2	
Hyperplasia, Squam Atypical, Focal, One					1	
Hyperplasia, Squamous		2 [1.5]	2 [2.0]		2 [1.5]	3 [1.7]
Inflammation, Pyogranulomat		4 [3.3]		2 [3.5]		3 [3.7]
Subcut Tiss, Edema	1 [2.0]					
Skin, Site Of Application	(2)	(0)	(0)	(2)	(0)	(0)
Skin, Site of Application	(34)	(36)	(35)	(34)	(36)	(36)
Abscess	1 [4.0]					
Cyst Epithelial Inclusion	12	5	3	7	4	6
Dermis, Inflammation, Chronic Active	33 [1.6]	34 [1.7]	32 [1.6]	32 [1.7]	34 [1.5]	32 [1.9]
Epidermis, Necrosis				2 [2.5]	3 [2.7]	2 [3.0]
Granuloma						
Hyperplasia, Squam Atypical, Focal, > Five		8	4	4	5	5
Hyperplasia, Squam Atypical, Focal, Five	1	2	5	3	5	4
Hyperplasia, Squam Atypical, Focal, Four	1	3	4	4	4	7
Hyperplasia, Squam Atypical, Focal, One	6	5	5	2	4	4
Hyperplasia, Squam Atypical, Focal, Three	1	6	7	5	6	4
Hyperplasia, Squam Atypical, Focal, Two	3	9	6	10	10	5
Hyperplasia, Squamous	20 [1.3]	35 [1.7]	31 [1.7]	33 [1.6]	36 [1.8]	34 [1.5]
Inflammation, Pyogranulomat	1 [1.0]	2 [3.0]			1 [4.0]	1 [2.0]
Subcut Tiss, Inflammation, Pyogranulomat		1 [3.0]				

MUSCULOSKELETAL SYSTEM

None

a - Number of animals examined microscopically at site and number of animals with lesion

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

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First Dose M/F: NA / NA
Lab: NCTR

SKH-1/NCTR Mouse MALE

NOCREAM 6.85SSL

NOCREAM 13.7SSL

VEHICLE 13.7SSL

ALOGEL3% 13.7SSL

ALOGEL6% 13.7SSL

WHLEAF3% 13.7SSL

NERVOUS SYSTEM

None

RESPIRATORY SYSTEM

None

SPECIAL SENSES SYSTEM

None

URINARY SYSTEM

None

a - Number of animals examined microscopically at site and number of animals with lesion

b - Average severity grade (1-minimal; 2-mild; 3-moderate; 4-marked)

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 First Dose M/F: NA / NA
 Lab: NCTR

SKH-1/NCTR Mouse MALE	WHLEAF6% 13.7SSL	CHARCL3% 13.7SSL	CHARCL6% 13.7SSL	AEMOD_LO 13.7SSL	AEMOD_HI 13.7SSL	NOCREAM 20.5SSL
Disposition Summary						
Animals Initially In Study	36	36	36	35	36	36
Early Deaths						
Accidentally Killed						
Moribund Sacrifice	2	2	4	3		3
Natural Death	1	1		2	1	
Survivors						
Moribund Sacrifice						
Natural Death						
Terminal Sacrifice	1				1	
Harvest	32	33	32	30	34	33
Animals Examined Microscopically	36	36	36	35	36	36
ALIMENTARY SYSTEM						
None						
CARDIOVASCULAR SYSTEM						
None						
ENDOCRINE SYSTEM						
None						
GENERAL BODY SYSTEM						
None						
GENITAL SYSTEM						
None						
HEMATOPOIETIC SYSTEM						
None						
INTEGUMENTARY SYSTEM						
Skin, Control	(36)	(36)	(36)	(34)	(36)	(36)

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First Dose M/F: NA / NA

Lab: NCTR

SKH-1/NCTR Mouse MALE	WHLEAF6% 13.7SSL	CHARCL3% 13.7SSL	CHARCL6% 13.7SSL	AEMOD_LO 13.7SSL	AEMOD_HI 13.7SSL	NOCREAM 20.5SSL
Abscess			1 [4.0]		1 [4.0]	1 [4.0]
Cyst Epithelial Inclusion	3	2	4	2	6	1
Dermis, Inflammation, Chronic Active	30 [1.1]	27 [1.3]	33 [1.4]	28 [1.3]	34 [1.4]	20 [1.2]
Developmental Malformation						
Epidermis, Necrosis	4 [3.8]	2 [3.5]		5 [4.0]	1 [4.0]	1 [4.0]
Granuloma			1			
Hyperplasia, Squam Atypical, Focal, One						
Hyperplasia, Squamous		1 [1.0]	1 [1.0]	1 [3.0]	1 [1.0]	
Inflammation, Pyogranulomat	3 [4.0]		1 [3.0]	4 [4.0]	2 [3.5]	1 [4.0]
Subcut Tiss, Edema						
Skin, Site Of Application	(1)	(0)	(1)	(0)	(1)	(0)
Skin, Site of Application	(35)	(36)	(35)	(35)	(35)	(36)
Abscess	1 [4.0]					1 [4.0]
Cyst Epithelial Inclusion	2	5	4	3	2	1
Dermis, Inflammation, Chronic Active	33 [1.5]	34 [1.7]	34 [1.7]	35 [1.6]	32 [1.8]	26 [1.3]
Epidermis, Necrosis	2 [3.0]	6 [3.7]	5 [2.8]	7 [3.7]	1 [4.0]	5 [4.0]
Granuloma	1					
Hyperplasia, Squam Atypical, Focal, > Five	8	4	5	4	7	5
Hyperplasia, Squam Atypical, Focal, Five	1	3	4	3	5	2
Hyperplasia, Squam Atypical, Focal, Four	4		10	8	4	6
Hyperplasia, Squam Atypical, Focal, One	4	4	5	5	8	7
Hyperplasia, Squam Atypical, Focal, Three	12	9	4	5	4	3
Hyperplasia, Squam Atypical, Focal, Two	5	14	2	5	5	9
Hyperplasia, Squamous	34 [1.7]	35 [1.5]	35 [1.5]	32 [1.6]	32 [1.7]	28 [1.8]
Inflammation, Pyogranulomat				2 [4.0]		
Subcut Tiss, Inflammation, Pyogranulomat						

MUSCULOSKELETAL SYSTEM

None

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Lab: NCTR

SKH-1/NCTR Mouse MALE

WHLEAF6% 13.7SSL CHARCL3% 13.7SSL CHARCL6% 13.7SSL AEMOD_LO 13.7SSL AEMOD_HI 13.7SSL NOCREAM 20.5SSL

NERVOUS SYSTEM

None

RESPIRATORY SYSTEM

None

SPECIAL SENSES SYSTEM

None

URINARY SYSTEM

None

**** END OF REPORT ****

a - Number of animals examined microscopically at site and number of animals with lesion
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